

**PATENT COOPERATION TREATY**  
**PCT**  
**INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY**  
(Chapter II of the Patent Cooperation Treaty)  
(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 15641PCT00	<b>FOR FURTHER ACTION</b>		See Form PCT/PEA416
International application No. PCT/DK2004/000265	International filing date ( <i>day/month/year</i> ) 07.04.2004	Priority date ( <i>day/month/year</i> ) 11.04.2003	
International Patent Classification (IPC) or national classification and IPC A61M25/00			
Applicant COLOPLAST A/S ET AL.			
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 6 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input checked="" type="checkbox"/> (<i>sent to the applicant and to the International Bureau</i>) a total of 2 sheets, as follows:</p> <ul style="list-style-type: none"> <li><input checked="" type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</li> <li><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</li> </ul> <p>b. <input type="checkbox"/> (<i>sent to the International Bureau only</i>) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>			
<p>4. This report contains indications relating to the following items:</p> <ul style="list-style-type: none"> <li><input checked="" type="checkbox"/> Box No. I Basis of the opinion</li> <li><input type="checkbox"/> Box No. II Priority</li> <li><input checked="" type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</li> <li><input type="checkbox"/> Box No. IV Lack of unity of invention</li> <li><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</li> <li><input type="checkbox"/> Box No. VI Certain documents cited</li> <li><input checked="" type="checkbox"/> Box No. VII Certain defects in the international application</li> <li><input checked="" type="checkbox"/> Box No. VIII Certain observations on the international application</li> </ul>			
Date of submission of the demand  11.02.2005	Date of completion of this report  09.08.2005		
Name and mailing address of the International preliminary examining authority:  European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016		Authorized Officer  Schönleben, J Telephone No. +31 70 340-2436	

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**Box No. I Basis of the report**

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:  
 international search (under Rules 12.3 and 23.1(b))  
 publication of the international application (under Rule 12.4)  
 international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the **elements\*** of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):

**Description, Pages**

1-13 as originally filed

**Claims, Numbers**

1-10 filed with telefax on 11.02.2005

**Drawings, Sheets**

1/2, 22 as originally filed

a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3.  The amendments have resulted in the cancellation of:

the description, pages  
 the claims, Nos.  
 the drawings, sheets/figs  
 the sequence listing (*specify*):  
 any table(s) related to sequence listing (*specify*):

4.  This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

the description, pages  
 the claims, Nos.  
 the drawings, sheets/figs  
 the sequence listing (*specify*):  
 any table(s) related to sequence listing (*specify*):

\* If item 4 applies, some or all of these sheets may be marked "superseded."

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**Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

the entire international application,

claims Nos. 10

because:

the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify):

the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

no international search report has been established for the said claims Nos. 10

the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form

has not been furnished

does not comply with the standard

the computer readable form

has not been furnished

does not comply with the standard

the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.

See separate sheet for further details

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**Box No. IV Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

**1. Statement**

Novelty (N)	Yes: Claims	
	No: Claims	1-9
Inventive step (IS)	Yes: Claims	
	No: Claims	1-9
Industrial applicability (IA)	Yes: Claims	1-9
	No: Claims	

**2. Citations and explanations (Rule 70.7):**

**see separate sheet**

**Box No. VII Certain defects in the international application**

The following defects in the form or contents of the international application have been noted:

**see separate sheet**

**Box No. VIII Certain observations on the international application**

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

**see separate sheet**

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**Re Item III.**

Independant claim 10 is referring to a method of treatment in the sense of Rule 67.1(IV) of the PCT for which the International Examination Authority is not required to carry out an examination (Article 34(4)(a)(I), Rule 67.1(iv) PCT).

Although claim 10 refers to a method of preparing a catheter, a method of use and thus a method of treatment is implicitly included in the claimed method since the consecutive method steps are solely carried out to perform subsequently a medical treatment in the sense of Rule 67.1(IV), such as introducing the catheter into the urinary canal for draining the bladder.

Consequently, according to Article 34(4)a(I), no opinion is to be established in respect to novelty, inventive step and industrial applicability.

**Re Item V.**

1. The following document is referred to in this communication:

D1 : US 2003/018293 A1 (TANGHOJ ALLAN ET AL) 23 January 2003 (2003-01-23)

2. INDEPENDENT CLAIM 1

- 2.1 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1 is not new in the sense of Article 33(2) PCT.

Document D1 discloses (see paragraphs 0093 and 0094, figures 15 - 18; the references in parenthesis applying to this document) a catheter assembly comprising a container (46) and at least one catheter element (42) with a proximal end adapted for insertion into the urinary canal and an opposite distal end, the container (46) comprising a cavity (48) adapted to accommodate at least a proximal section of said catheter element, said catheter assembly further comprising a catheter handle (44, see paragraph 94, line 2) adapted to be interlocked with said catheter element, the handle (44) comprising a sleeve section adapted to surround a portion of said container, whereby the handle is further adapted to be separated from the catheter element and from the container (see fig. 15 of D1: When the flange 45 of handle 44 is engaged in groove 51 of seal 50 (see paragr. 94) container 46 is free to be disconnected from the seal; since flange 45 of handle 44 must have a certain elasticity in order to be able to override the end of seal 50, after movement of the handle to the left, the handle is also adapted to be seperated from the catheter).

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**3 DEPENDENT CLAIMS 2-9**

Dependent claims 2-9 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty in the sense of Article 33(2) PCT, since D1 discloses all features of claims 2 - 9 (see paragraphs 0093 - 0095).

**Re Item VII**

Claims 3, 4 and 6 - 9 do not meet the requirements of Rule 6.4 PCT.

The features of claims 1 - 9 are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).

Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the document D1 is not mentioned in the description, nor is this document identified therein.

**Re Item VIII**

The terms "proximal" and "distal" are applied in an opposite sense than used according their definitions (see Webster Dictionary).

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**Applicant: Coloplast****Application No.: PCT/DK2004/000265****Our ref: 15641PCT00****5 New Claims - February 2005, fair copy**

1. A catheter assembly comprising a container and at least one catheter element with a proximal end adapted for insertion in a urinary canal and an opposite distal end, the container comprising a cavity adapted to accommodate at least a proximal section of said catheter element, said catheter assembly further comprising a catheter handle adapted to be interlocked with the catheter element, the handle comprising a sleeve section adapted to surround a portion of said container characterized in that said catheter handle is adapted to be separated from said catheter element and from said container.
- 10 2. A catheter assembly according to claim 1, wherein said catheter handle is adapted to be attached to said container assembly.
- 15 3. A catheter assembly according to claim 1 or 2, wherein said catheter handle is shorter than said container or shorter than said catheter element.
4. A catheter assembly according to any of the preceding claims, wherein a distal section of said catheter element has at least one protruding part and wherein a proximal compartment of said cavity is adapted to accommodate a proximal section of said catheter, said proximal compartment having a distal opening zone with exclusion means adapted to exclude said distal section of said catheter element from entering said proximal compartment.
- 20 5. A catheter assembly according to claim 4, wherein said exclusion means comprises a radially inwardly extending protrusion in the cavity.
- 25 6. A catheter assembly according to claim 4 or 5, wherein at least a part of said distal opening zone is flexible.
7. A catheter assembly according to any of the preceding claims, further comprising a lubricating medium.

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8. A catheter assembly according to any of the preceding claims, wherein at least a portion of said catheter element has a hydrophilic coating.
9. A catheter assembly according to any of the preceding claims, wherein said container comprises sealing means for sealing said cavity.

5      10. A method for preparing a catheter device, said method comprising the steps of:

- a) providing a catheter assembly comprising a container assembly, said container assembly comprising a catheter element, which has a proximal end adapted for insertion in a urinary canal and an opposite distal end, the container assembly further comprising a container with a cavity adapted to accommodate at least a proximal section of said catheter element and a catheter handle comprising a sleeve section adapted to surround a portion of said container,
- b) detaching the catheter handle from the container assembly,
- c) connecting the catheter handle to the catheter element,
- d) removing the catheter element from the container.

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